Notice of Allowability	Application No.	Applicant(s)	
	10/011,855	BAUMANN ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *02/18/2005*.

2. ☒ The allowed claim(s) is/are *1,8,11-13 and 23-27*.

3. ☐ The drawings filed on _____ are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *02/18/2005* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Bao Qun Li

JEFFREY S. PARKER
PRIMARY EXAMINER

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

2. Authorization for this examiner's amendment was given in the telephone interviews with Barry Wilson on February 17 and 18 of 2005.

The application has been amended as follows:

Claim 1 (current amended).

In line 2 after "nucleic" deleted "acids" and inserted --- acid ---

In line after line 2 after "comprising' and inserted a new paragraph of a step (a) as following:

--- (a) --- introducing a phage-HCV nucleic acid hybrid into said sample, wherein said hybrid comprises a phage sequence and a HCV sequence; ---

In line 3, deleted "(a)" and inserted --- (b) ---

In line 4, before "using" inserted --- and generating a phage-HCV amplicon ---

In line 5,before "with" deleted "acids" and inserted --- acid ---

In line 6, deleted "(b)" and inserted --- (c) --- before "with" deleted "acids" and inserted --- acid --- before " oligonucleotide" inserted --- HCV ---

In line 7, after "probe" deleted " consisting of the sequence set forth in SEQ ID NO: 3" and inserted --- complementary to the HCV sequence ---

In line 8, after "nucleic" deleted "acids" and inserted ---- acid --- after "wherein said" inserted --- HCV---

In line 9, before "and" inserted another new paragraph of step (d)

--- (d) hybridizing said phage-HCV nucleic acid amplicon to a control oligonucleotide probe complementary to the phage sequence wherein said probe is conjugated to a detectable label that generates a detectable signal upon said cleavage; ---

In line 10, deleted " (c)" and inserted --- (e) ---

In line 11, after "nucleic" deleted acids" and inserted "acid"

Claim 1 is rewritten as follow:

1. A method for detecting the presence or amount of HCV nucleic acid in a test sample, comprising:

(a) introducing a phage-HCV nucleic acid hybrid into said sample, wherein said hybrid comprises a phage sequence and a HCV sequence;

(b) reverse transcribing and amplifying HCV nucleic acid if presence in said sample and generating a phage-HCV amplicon using a pair of oligonucleotide primers having the sequences set forth in SEQ ID NO: 1 and SEQ ID NO: 2;

(c) hybridizing said amplified HCV nucleic acid with an HCV oligonucleotide probe complementary to HCV sequence in the presence of an enzyme that cleaves said probe when said probe hybridizes to said HCV nucleic acid, wherein said HCV probe is conjugated to a detectable label that generates a detectable signal upon said cleavage;

(d) hybridizing said phage-HCV nucleic acid amplicon to a control oligonucleotide probe complementary to the phage sequence wherein said probe is conjugated to a detectable label that generates a detectable signal upon said cleavage; and

(e) detecting a signal from said detectable label, wherein said signal indicates the presence or amount of HCV nucleic acid in said test sample.

Canceled claims 9-10.

Claim 13 (current amended) In line 1 after "wherein" deleted "lambda" and inserted --- said --- In line 2 before "are" deleted "hybrids" deleted "hybrids" and inserted --- hybrid, after "nucleic" deleted "acids" and inserted --- acid ---

Added the following new claims:

23. (new) The method of claim 1, wherein said HCV probe comprises a sequence set forth in SEQ ID NO: 3,

24. (new) The method of claim 1, wherein said phage sequence is from lambda phage.

25. (new) The method of claim 24, wherein said control probe comprises the sequence set forth in SEQ ID NO: 6.

26. (new) The method of claim1, wherein said control probe is conjugated to 6-carboxyfluorescein (FAM) and 6-carboxytertramethylrhodomaine (TAMRA).

27. (new) The method of claim 1, wherein said phage-HCV nucleic acid hybrid comprises an RNP polymerase

Claims 1, 8, 1-12, 23-27 are allowed.

3. The following is an examiner's statement of reasons for allowance:

4. The claimed invention is drawn to a unique method for detecting presence and an amount HCV in the sample by using a HCV-phage lambda hybrid in the detection system in addition to a standard positive control of a HCV sequence. This unique approach increases the accuracy and consistence of the HCV detection method and it is not taught and suggested by prior art. The support of new claims 23-27 can be found in the original claim 1, 9-10 and line 7-8 of paragraph [0052] of specification on page 15.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

02/19/2005

JEFFREY S. PARKER
PRIMARY EXAMINER